Adopted December 13, 1997 by the Managed Health Care Improvement Task Force

IMPROVING THE DELIVERY OF CARE AND THE PRACTICE OF MEDICINE FINDINGS AND RECOMMENDATIONS

I. INTRODUCTION

A. Organizations Are Making Medical Decisions

Today, doctors and patients who agree on a course of necessary care may have that course altered either by delay or denial by an HMO or its utilization management designee. In theory, the opportunity to measure an impending medical decision against outcomes research, practice guidelines and relevant clinical algorithms, should ultimately work to patients' benefit. Some have argued that prior authorization/concurrent review is a key element separating managed care from traditional unmanaged, fee-for-service "indemnity" insurance. In addition to controlling costs, prior authorization/concurrent review can, in some cases, strengthen the quality of care by identifying procedures, tests or other treatments that may be unnecessary or contribute to error.[1] But the evidence of effectiveness is mixed.[2]

The perception that treatment decisions are being reviewed by an appropriately credentialed physician, with adequate knowledge of the case at hand, is also mixed. In some cases, care may be compromised when a practitioner for adults is asked to render a pediatric opinion.[3] Some have argued that certain children and adults with chronic diseases would benefit from receiving their primary care from specialists in the chronic disease (Please see the Task Force paper on Physician-Patient Relationship).[4,5] While major stakeholders in the health care industry may disagree, the public perception is that the health plan[6] reviewers are a heterogeneous group with mixed qualifications and that prior authorization/concurrent review sometimes focuses too heavily on cost and causes inappropriate delays or denials in care without due medical cause.

B. Cost Matters When Practicing Medicine

Purchasers, employers and consumers want slower growth in the cost of medical care and less costly health benefit arrangements (please see the Task Force paper on Impact of Managed Care on Quality, Access and Cost). Yet, everyone expects maximum care when they become sick. Some consumers are not confident that they are receiving the highest quality of care when health plans and providers endeavor to practice cost-effective medicine by limiting selected services (see the Task Force paper on Physician-Patient Relationship). Legislators are trying to respond to constituents who have become mistrustful of the health care system.

C. In the Face of Limited Industry Action, Legislators Respond

Unfortunately, the concern has been raised that legislators, while trying to solve these problems, are practicing medicine. Nationally and locally politicians are, implicitly if not explicitly, legislating medical practice. The

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[1] California Association of Health Plans, "Utilization Management in Health Plans: A Critical Component of Quality Assurance," attachment to a letter to Chairman A. Enthoven, September 15, 1997.

[2] Schlesinger, M. J., Bray, B. H. and Perreira, K. M., "Medical Professionalism Under Managed Care: The Pros and Cons of Utilization Review," *Health Affairs*, 16:1, January/February 1997, 106-124.

[3] Public Testimony of Mr. Harry Christie before the Managed Health Care Improvement Task Force, August 7, 1997. Mr. Christie detailed the many frustrations and roadblocks encountered in trying to obtain specialized pediatric services for his daughter Carly.

[4] California Medical Association, "Making Managed Care Work," Presentation to the Managed Health Care Improvement Task Force, September 1997.

[5] The Robert Wood Johnson Foundation, "Sick People in Managed Care have Difficulty Getting Services and Treatment, New Survey Reports," Press Release, June 28, 1994.

[6] Throughout this paper, the term "health plan" refers to health insurance arrangements or health benefits financial intermediaries.

respected *New England Journal of Medicine* has declared that "medical imperialism is obsolete."[7] The Task Force believes that the practice of medicine is a multi-disciplinary, multi-professional, team effort and that physicians are no longer the sole arbiters of medicine. However, neither Congress, nor the California Legislature, nor health plan executives who are not health care providers licensed to practice in the State of California, should be medical practice team members. Appropriately credentialed professionals practicing scientific, evidence-based medicine should be the arbiters of cost-effective medical care. They should also be responsible for continuously improving the quality of medical care.

D. Variation in Practicing Medicine Clouds What is Medically Necessary

A basic premise is that physicians and other providers want to practice excellent, high quality medicine. Yet research shows wide variations in both medical practice and resource use, without evidence of corresponding differences in either medical need or health outcomes.[8] Significant practice pattern variation, however, raises important and complex questions. "Which rate of surgery or therapy is right?" "Are some patients being treated more conservatively with the same or better outcomes?" "Do certain rates of surgery or therapy reflect patient preferences and values more than others?" "What is the effect on a population's health?" Variation also suggests that providers sometimes differ on what is medically necessary. In addition, some patients may want unnecessary services(See the Task Force paper on Impact of Managed Care on Quality, Access and Cost). Behavior of both physicians and patients is frequently driven by the inherent uncertainty in medical care. The need to reduce this uncertainty and consequent variation is compelling and challenging.

The practice of medicine depends on the interrelationship among diagnostic evaluations, clinical judgments, surgery, therapies and drugs, and the interaction and communication between providers and patients. A review of a provider's pattern of medical decisions is very valuable when it can be done over a long enough period of time and with enough treatment and outcome data points to be able to statistically evaluate the provider's delivery of care. This evaluation should be done using state of the art information about clinical outcomes relative to the resources prescribed. This evaluation would provide a more scientific basis for establishing medically necessary, high quality care and accountability for medical practice.

II. FINDINGS AND RECOMMENDATIONS

A. Modify Prior Authorization/Concurrent Review

Decision quality should be improved by encouraging the use of practice guidelines, clinical pathways, careful selection and pre-credentialing of providers, retrospective utilization review and outcomes research in medical decision making. If a provider's referral patterns are appropriate and outcomes are good, the provider should be considered to have demonstrated exemplary practice and the HMO should cease to require prior authorization/concurrent review for a finite period of time. Many alternatives to prior authorization/concurrent review are possible. There is room in the marketplace for a variety of innovative, incremental and expedited referral programs.[9,10] However, for innovations to occur, better data interchange is needed. Many health plans delegate utilization review and management to their contracting medical groups/IPAs and other independent utilization management designees. Those health plans that delegate this responsibility cannot monitor quality and compliance without encounter data. To be useful,

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[7] Kassirer, J., "Practicing Medicine Without A License—The New Intrusions by Congress," *New England Journal of Medicine*, 336:24, June 12, 1997, 1747.

[8] Center For The Evaluative Clinical Sciences Dartmouth Medical School, *The Dartmouth Atlas of Health Care*, ed. Wennberg, J. E. and Cooper, M. M., Center For Health Care Leadership of the American Hospital Association, 1996.

[9] American Association of Health Plans, "AAHP Fact Sheets: Access to Care," July 29, 1997.

[10] Gold, M. R., et al., "A National Survey of the Arrangements Managed Care Plans Make with Providers," *New England Journal of Medicine*, 333:25, December 21, 1995, 1678-1683.

encounter data should include diagnoses and procedures at the treatment level, information which medical groups have to date viewed as proprietary. Health plans should create incentives for medical groups and IPAs to provide such data. Ideally, the private sector will correct this data communication problem.

Purchasing groups should be encouraged to work with the scientific advisory arms of the health plans and medical groups to implement specific practice guidelines, clinical pathways and outcome studies for modifying the prior authorization/concurrent review process. Realistically, encounter data at the patient and provider level will have to be available for the above to occur. Patients with catastrophic diseases deserve special consideration. For example, in certain cancer cases treatment and therapy is time sensitive, and delays or denials of care can have severe and unintended consequences. In many of these cases there are existing, accepted and respected clinical guidelines. Prior authorization/concurrent review should not be a barrier to care in these cases. In all situations, it is important to recognize that medical science and practice are constantly changing and a rigid codification of medical practice through attempted legislation should be avoided.

1. Recommendation to Modify Prior Authorization/Concurrent Review

(a) The Task Force recommends that health plans incorporate provider pre-credentialing and the use of practice guidelines, clinical pathways, retrospective review (as opposed to prior authorization/concurrent review) and outcomes-based data into their established utilization monitoring processes.

(b) The Task Force recommends to the health plans, medical groups/IPAs and their designees, that they develop utilization monitoring processes based on statistically valid data on patterns of care and patient outcomes, or professional consensus, that are sensitive to the needs of various populations, including vulnerable populations. These data sets or professional consensus may then form the basis on which alternatives to prior authorization can be based (See Task Force paper on New Quality Information Development).

(c) The Task Force recommends to the health plans and their designees that they develop and implement strategies that allow providers who demonstrate an exemplary practice profile to practice medicine with automatic approval for a defined scope of practice. A probationary period of up to, but not more than, two years may be employed to assess provider utilization in determining eligibility for automatic approval status. Plans may continue to require providers to obtain verification of eligibility, coverage and approval for the setting in which the procedure is to be performed.[11] Health plans may develop appropriate and periodic review mechanisms to ensure that providers continue to demonstrate an exemplary practice.

(d) The Task Force recommends to the health plans and their designees that they eliminate prior authorization and concurrent review for patients with catastrophic conditions being treated by pre-credentialed providers for which outcomes based protocols have been developed and broadly accepted (e.g., pediatric oncology).

[11] Eligibility is a distinct concept from coverage. Eligibility refers to the criteria that an employer uses to determine whether or not to offer health benefits to an employee as well as the criteria that a health plan uses to determine whether a patient is entitled to benefits through their employer. In the plan's case, the plan would want to know if a patient was still employed by Company A and whether the premium had been paid. Coverage refers to the list of benefits delineated by contract between Company A and the plan. This list usually includes hospital care, physician services, routine exams, maternity care, prescription drugs, etc.

(e) The Task Force recommends that there be a review and report by the year 2000 on how the private sector has modified the prior authorization/concurrent review process to recognize exemplary care or an equivalent modification. (The report should include consideration of whether the state entity(ies) for regulation of managed care[12] should consider making the necessary changes a requirement of health plan licensure or accreditation.)

(f) Where prior authorization/concurrent review is required, denials of care must include a review by appropriately qualified, credentialed individuals.

B. Improve Formulary Effectiveness

Ideally, the appropriate practice of medicine effectively integrates clinical judgment, diagnostic evaluations, surgery, therapies and drugs to form and inform clinical pathways, practice guidelines, and outcomes research. Pharmaceutical prescribing practices and costs are an important and much debated component of this process.[13] Pharmaceutical costs are rising rapidly; formularies are one tool to manage them. To lower pharmaceutical costs and maintain affordable drug coverage, a case can be made that the individual physician's choice of drugs should be informed, guided and perhaps constrained by a committee of his or her peers. Flexibility should be built into this process to allow for individual physician and patient variation. It is not appropriate to apply strict population standards to individual patients when prescribing drugs. Some drugs work for some patients, but not for others. The involvement of physicians in formulary development is key to changing physician practice.

Provider groups in California have an average of 15 managed care contracts.[14] This means that when prescribing a drug, a physician may have to consult several if not 15 drug formularies. Providers have to figure out which health plan covers their patient, then which drugs are in its formulary, and then spend time on the phone requesting exceptions. This is bound to raise administrative costs and complexity and reduce efficiency and effectiveness. The situation can be worse – indeed bordering on the impossible – for the doctor in individual practice who belongs to several IPAs, each of which contracts with 15 different managed care plans.

2. Recommendation to Improve Formulary Effectiveness

(a) Consumers should be ensured that they will be fully informed of their rights to prescription drugs offered by a health plan, and those rights should include, but not be limited to the following:

(1) All health plans and their designees (whether pharmaceutical benefits managers or medical groups) that offer prescription drug benefits and use a formulary, must periodically publish their formulary drug lists and make them available to any member of the public upon request subject to reasonable costs.

(2) All health plans and their designees (whether pharmaceutical benefits managers or medical groups) that offer prescription drug benefits and use a formulary must publish a description of the process by which their formulary is developed and reviewed.

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[12] Throughout this paper, the term "state entity(ies) for regulation of managed care" refers to the Department of Corporations, the Department of Insurance, and its/their successor.

[13] Horn, S., et al., "Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project," *The American Journal of Managed Care*, II:3, March 1996, 253-264.

[14] American Medical Association, *Physician Marketplace Statistics 1996*, Center for Health Policy Research, Chicago, 1996.

(3) Health plans and their designees (whether pharmaceutical benefits managers or medical groups) must have in place, and make known to consumers and providers, timely exception processes by which a physician or a patient (with his or her physician's support) may secure quick approval for medically necessary non-formulary drugs.

(4) When a health plan removes a drug from its formulary, it should be required to allow the patient to continue receiving the removed drug for an ongoing condition unless the treating physician prescribes a new agent or the drug is no longer considered safe and effective for the patient's medical condition based on appropriate medical evidence.

(5) The state entity(ies) for regulation of managed care should be directed to investigate periodically and report publicly on health plan and contracting medical group compliance with these recommendations.

(b) Health plans that develop a formulary for their members should include input from practicing plan physicians with relevant expertise, input from specialty societies and other relevant data when composing the formulary.

C. Clarify the Benefit Language in Health Insurance Contracts

Benefit language has traditionally relied on vague terms with no precise meaning. Health plans have covered most things thought to be "medically necessary" or "appropriate" by providers or that met a "community standard." Since no consensus exists as to how to make benefit language more precise, it is important to define the criteria by which medical necessity is applied so that it can lead to improved quality, improved health outcomes, improved functional outcomes and better adherence to the scientific basis of treatment decisions. Further study is needed in this area.

Debate about coverage and treatment decisions is not complete without more discussion about experimental treatments and therapies. The Friedman-Knowles bill (AB 1663) passed in 1996, makes provision for appeals after an experimental treatment decision is denied. However, the question remains as to when a treatment crosses the line from experimental to accepted and non-experimental. It would be desirable for an independent, expert review panel of physicians and health plans to review the scientific findings to determine when there is sufficient evidence to reclassify therapies from experimental to proven treatments, which are to be included in the standard of clinical care. Presently, a consistent, industry-wide process for this evaluation does not exist.

3. Recommendation to Clarify Benefit Language in Health Insurance Contracts

(a) Create a "blue ribbon" public/private work group of major stakeholders[15] to study and recommend changing the benefit language in health plan contracts. The panel should have a state-wide strategy for implementing benefit language changes within two years. The state should require that implementation of these changes, where feasible, be phased-in within two subsequent years. Among the issues the panel should consider are:

- For most consumers the decision to pay for care is synonymous with the decision to receive care, since few consumers can afford to purchase most care out of pocket.

[15] The intention of the Task Force is that stakeholders include, but are not limited to, consumer groups, including representatives of vulnerable populations, providers, provider groups, health plans, and purchasers.

- Benefit definitions should consider the needs of seniors, children, individuals with disabilities and other vulnerable populations and should consider the objective of maximizing functional capacity and the inclusion of benefits to maintain function and to slow or prevent deterioration of function.
- Revisions of benefits criteria should consider the impact of reducing or eliminating coverage for care.
- Studies of the issues inherent in changing benefit language should consider the transition from vague, imprecise terms to language intended to maximize quality outcomes, health outcomes, functional outcomes and the scientific underpinnings of treatment decisions while controlling costs.

(b) The state entity(ies) for regulation of managed care should convene an appropriate panel representing all stakeholders and having appropriate clinical expertise to accept, catalogue and organize data concerning agreement on standard of care and medical appropriateness in reference to treatment issues.

This panel can review data presented as evidence-based or consensus-based pertaining to clinical modalities. By defining standard of care and medical appropriateness, this panel could also define experimental care and could help determine when sufficient data become available for a new clinical approach to transition treatments from experimental to clinical standard of practice. The panel could further catalyze needed clinical trials where appropriate data have yet to be developed for making such determinations.

This panel could also encourage all payors to identify and support experimental protocols in certain circumstances of life threatening or limiting illnesses.